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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/733,306

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EXAMINER

EPPS FORD, JANET L

ART UNIT

PAPER NUMBER

1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/733,306

Applicant(s)

SCHWARZ, MARGARET A.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-02-06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-11,17-19,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-11,17-19,47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 1-2, 7-11, 17-19 and 47-48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et al. (US 2003/0215421) and Salfeld et al. (US 6914128), in view of Stern et al. (US 5,641,867), for the reasons of record.
3. Applicant's arguments filed 11-02-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that "[t]he references in their totality for the complete disclosure that they provide...fail to direct one of skill in the art to arrive at a method of facilitating vascular growth in cardiac muscle of a human subject in need of such treatment..." According to Applicants, "[o]ne skilled in the art would merely surmise that antibodies that bind to EMAP II may be used as an adjunct therapy to a primary treatment for disorders described therein. "

First, it is noted that the instant claims are drawn to methods "comprising" the administration of an antibody that specifically binds to EMAP II of SEQ ID NO: 4. Therefore, contrary to Applicant's assertions if the totality of the prior art teaches methods comprising the administration of compositions comprising an antibody directed to EMAP II, for the treatment of the disorders according to the present invention, then absent evidence to the contrary, the prior art is interpreted as reading on the claimed invention. Secondly, to summarize what the prior art teaches: 1) McDonald et al.

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describe the treatment of diseases associated with chemokine expression as induced by secreted pro-inflammatory cytokines primarily as chemo-attractants and activators of specific leukocyte cell sub-types (see background of invention 1st paragraph), wherein the diseases include: ischemia, myocardial infarction, rheumatoid arthritis, and atherosclerosis. The reference describes a variety of compounds that can be used for the treatment of these diseases, among these are included *conjugates* comprising antibodies targeting the non-chemokine cytokine receptor EMAP II (see pages 22-23, paragraphs [0246]-[251]). Moreover, although antibodies targeting EMAP II are disclosed in a list among others, it is clear that these antibodies are disclosed as being functionally equivalent antibodies specific for a non-chemokine cytokine receptor, see for example paragraph [0251], which states:

[0251] In some instances, the antibody can be specific for a non-chemokine cytokine receptor EMAP II, GM-CSF, G-CSF, M-CSF, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-12, IL-13.

Therefore, although there is some "picking and choosing" in this instance, the "picking and choosing" is from among a group of equivalent antibodies specific for a specific class of cytokine receptor.

2) Salfeld et al. teach the use of human antibodies that bind human IL-12 for the treatment of diseases. This reference teaches that IL-12 plays a role in the pathology of a variety of diseases involving immune and inflammatory elements. Some of these diseases include atherosclerosis, and cardiomyopathy. This reference also teaches that antibodies targeting IL-12 can be used in combination with other antibodies for the

treatment of the diseases associated with IL-12 expression, among these includes antibodies targeting EMAP II.

As stated above, although this reference describes the use of antibodies targeting EMAP II in combination with antibodies targeting IL-12, the instant claims are drawn to methods *comprising* the administration of antibodies targeting EMAPII. Therefore, the use of an additional component disclosed in the methods of treatment described by Salfeld et al. does not read away from the claimed invention.

3) Stern et al. discloses antibodies which specifically bind to EMAP II polypeptide as set forth in SEQ ID NO: 4, (see SEQ ID NO: 37). Stern et al. discloses the purified antibodies in a buffer (see col 13-14).

Moreover, Applicant concluded that “[N]one of the cited references teach or suggest using EMAP II for the treatment described therein.” In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., namely the use of EMAP II for treatment) are not recited in the rejected claim(s). The instant claims are drawn to methods comprising the administration of antibodies that specifically bind to EMAP II, and not to methods comprising the administration of EMAP II polypeptide.

Contrary to Applicant's assertions, and in the absence of any evidence of unexpected results, it would have been obvious to the ordinary skilled artisan, at the time of the instant invention, to modify the methods of McDonald et al. and Salfeld et al. to comprise the use of the purified EMAP II antibody disclosed in Stern et al. One of ordinary skill in the art would have been motivated to make this modification since the

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compounds of Stern et al. are functionally equivalent EMAP II antibodies as disclosed in McDonald et al. and Salfeld et al.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE